EXPERTS AT YOUR FINGERTIPS

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JUN - 5 2006

Premarket Notification [510(k)] Summary

K061006

March 31, 2006

Trade Name:	*IKOEngelo*™
Common Name:	Radiation Therapy Simulation accessory
Classification Name:	Radiation Therapy Simulation System, Product Code: KPQ (per 21 CFR 892.5840)
Manufacturer's Name:	IKOEtech, LLC.
Address:	3000 Richmond, Suite 200 Houston, TX 77098
Corresponding Official:	Ms. Huimin Chao, LLM
Title:	President
Telephone:	(713) 600-2410
Fax:	(713) 600-2411
Predicate:	IMPAC Medical Systems, Inc. QwikSIM Virtual Simulation System, 510(k) #: K013531.

Device Description:

The *IKOEngelo* device is a software system that will assist radiation oncologists, with the assistance of physicists and dosimetrists, to more efficiently perform contour delineation of the tumor target and normal tissue on patient's CT images.

The sequence of events is illustrated in the following bullet items and diagram:

- Import patient's CT images.
- Select the proper Expert Case (including the CT image data set and contours) to match patient's CT.

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- Automatically fuse the images to align patient's CT image data sets with those of the Expert Case.
- Run deformable segmentation to auto-contour on the patient's CT images.
- Review patient's contours and modify them if necessary.
- Approval by qualified radiation oncologist.
- Export patient's CT with its contours to the treatment planning system used by the facility.

Intended Use: The *IKOEngelo*™ System is intended for use in tumor and normal tissue contour delineation to support the radiotherapy treatment planning process

Technological Characteristics: See the attached "Predicate Comparison Table".

Predicate Comparison Table

#	Feature	**IMPAC Medical Systems, Inc. QwikSIM (K013531)**	**IKOEtech *IKOEngelo*™**
1	Intended Use	QwikSIM is a radiation therapy virtual simulation system for patient image review, target and critical structure delineation, and geometric treatment planning.	The *IKOEngelo*™ System is intended for use in tumor and normal tissue contour delineation to support the radiotherapy treatment planning process.
2	Image Study Import	Dicom[3]	Dicom[3]
3	Treatment Planning Connectivity	DICOM CT SCP and DICOM RT Structure Set SCP/SCU interface modalities.	DICOM CT SCP and DICOM RT Structure Set SCP/SCU interface modalities.

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K06 1006

4	Flexible Image Display	Multiple-image views and allows side-by-side views for comparison, displaying the following perspectives: Slice View, Orthogonal Multi-Planar Reconstructed View, and Digital Scout View.	Multiple-image views and allows side-by-side views for comparison, displaying the following perspectives: Slice View, Orthogonal Multi-Planar Reconstructed View.
5	Image Viewing Tools	Tools for image review include zoom and pan tools for reviewing MPR/Slice planes, and tape measure and protractor controls.	Tools for image review include zoom and pan tools for reviewing MPR/Slice planes, slice indicators, tape measure, CT number displayer, and isocenter lines.
6	Contour Source	Anatomy Templates	Expert Case Library
7	Automatic Contouring	Based on pre-defined CT thresholds	Deformable registration and segmentation.
8	Contour Expansion	2D inflation of anatomical objects with specified margins.	N/A
9	Image Fusion	N/A	Auto and manual fusion
10	Contours Review	Side-by-side only	Side-by-side with image linking to scroll through simultaneously.
11	Contour Modification Tools	Point-click draw contour tool.	Nudge contour, cut contour, draw contour and create new contour tools.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Ms. Huimin Chao
President
IKOTech, LLC
3000 Richmond, Suite 200
HOUSTON TX 77098

JUN - 5 2006

Re: K061006
Trade/Device Name: IKOEngelo™
Regulation Number: 21 CFR §892.5840
Regulation Name: Radiation therapy simulation system
Product Code: KPQ
Regulation Number: 21 CFR §892.5050
Regulation Name: Medical charged-particle radiation therapy system
Product Code: MUJ and IYE
Regulatory Class: II
Dated: April 1, 2006
Received: April 11, 2006

Dear Ms. Chao:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Tab 3

Indications For Use

510(k) Number (if known): ~~Pending~~ K061006

Device Name: *IKOEngelo™*

Indications for Use:

The *IKOEngelo™* System is indicated for use by radiation oncologists, medical physicists, and medical dosimetrists for tumor and normal tissue contour delineation to support the radiotherapy treatment planning process. The resulting information may then be exported to a treatment planning system for dose calculation.

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061006

Prescription Use ✓ ~~AND~~/OR Over-The-Counter Use ____

(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)